

Title: **Quality Control Record Sheet
VGCC Ab QC Data**

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Approved by: J Davies

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Kit Lot Number: LK262 Kit Expiry Date: 26 June 2026

Kit Manufacture Date: 09 April 2026

¹²⁵I-VGCC for total binding lot number: LT262 Expiry Date: 26 June 2026

¹²⁵I-VGCC for non-specific binding lot number: NS262 Expiry Date: 26 June 2026

Dilution buffer lot number: 256LB Expiry Date: 26 June 2026

Anti-human IgG lot number: 29LGf Expiry Date: 26 June 2026

Wash solution lot number: 196LW Expiry Date: 26 June 2026

Negative control lot number: 22LNh Expiry Date: 26 June 2026

Positive control lot number: 27LPf Expiry Date: 26 June 2026

At Manufacture Date: 6059 dpm = 1 fmole

At QC Assay Date¹: 5785 dpm = 1 fmole (conversion factor A)

Counter Efficiency: 75.8 % (B) ² Positive control range: 169 ± 76 pmol/L

Sample	NSB		T			
	Mean cpm - background	fmol/ Pellet (E)	Mean cpm - background	fmol/ pellet (D)	¹²⁵ I-conotoxin labelled VGCC bound (pmol/L serum)	pmol/L serum VGCC Ab (after subtraction of negative control)
Total counts	16361	3.731	15882	3.622		
Negative control	314	0.072	305	0.070	-0.8 (G)	-
Positive control	330	0.075	1818	0.415	135.7 (F)	136.6 (H)
Test sample 1b	372	0.085	2429	0.554	187.6 (F)	188.5 (H)
Test sample 2b	215	0.049	905	0.206	62.9 (F)	63.8 (H)
Test sample 3c	273	0.062	1262	0.288	90.2 (F)	91.0 (H)
Test sample 4b	307	0.070	1357	0.309	95.8 (F)	96.6 (H)
Test sample 5d	292	0.067	1526	0.348	112.6 (F)	113.4 (H)

Assay date (weeks after QC assay)	Decay factor (C)	Assay date (weeks after QC assay)	Decay factor (C)
Up to 1 week	1.00	+ 6 – 7 weeks	0.61
+ 1 – 2 weeks	0.92	+ 7 – 8 weeks	0.56
+ 2 – 3 weeks	0.85	+ 8 – 9 weeks	0.52
+ 3 – 4 weeks	0.78	+ 9 – 10 weeks	0.48
+ 4 – 5 weeks	0.72	+ 10 – 11 weeks	0.44
+ 5 – 6 weeks	0.66		

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

QC Assay Date¹: 13 April 2026

Performed by: A. Huckle

Signature: A. Huckle

Position: Snr Technician

Authorised by: DR G Flood

Signature: G Flood

Position: Head of Quality Control

Date: 16th APR 2026